Summary of Safety and Effectiveness Data
(As required by 21 CFR 807.92)

JUN 10 2011

Date Prepared: January 10, 2011
Revised: June 8, 2011

Submitted by: Byrne Medical Inc.
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Indications for Use:

The DEFENDO™ Y-Opsy Irrigator is intended to enable simultaneous irrigation and instrumentation in the endoscope's biopsy channel.

Description:

The DEFENDO™Y-Opsy Irrigator is a sterile, disposable, single patient use, biopsy valve with a side port backflow valve for irrigation. It provides access for endoscopic device passage, helps maintain sufflation, and minimizes leakage of biomaterial from the biopsy channel during endoscopic procedures. The backflow valve prevents the potential of cross contamination between patients the device's diaphragm (slit) minimizes leakage from the biopsy channel while reducing the healthcare professional's exposure to biomaterials as endoscopy instruments are withdrawn.

Substantial Equivalence:

The DEFENDO™ Y-Opsy Irrigator is substantially equivalent to the Byrne Medical Endogator® System Y-Connector and the Byrne Medical DEFENDO™ Biopsy Valve.

The Byrne Medical, Inc., DEFENDO™ Y-Opsy Irrigator and predicate device's (Byrne Medical Endogator® System Y-Connector, K092429 and Byrne Medical DEFENDO™ Biopsy Valve, K090851) are in Class II, 21 CFR 876.1500.

The predicate devices' are manufactured by Byrne Medical Inc., Conroe, Texas. The Byrne Medical, Inc., DEFENDO™ Y-Opsy Irrigator has been determined to meet the equivalence decision making process as detailed by the "510(k) Substantial Equivalence Decision-Making Process Flowchart" (updated July 30, 2007).

Table 14-1: Comparison of features and principles of operation between the DEFENDO™ Y-Opsy Irrigator and Predicate Devices' (Byrne Medical Endogator® System Y-Connector and Byrne Medical DEFENDO™ Biopsy Valve)

Characteristic	Byrne Medical DEFENDO™ Y-Opsy Irrigator	Byrne Medical EndoGator® System with Y-Connector	Byrne Medical Defendo™ Biopsy Valve	Same?
Trade Name	DEFENDO™ Y-Opsy Irrigator	EndoGator® System	DEFENDO™ Biopsy Valve	N/A
510(k) Doc. No	K110088	K092429	K090851	N/A
Product Code	ODC	FEQ	ODC	No
Regulation#	876.1500	876.1500	876.1500	Yes
Class	II	II	II	Yes
Review Advisory Committee	Gastroenterology/Urology	Gastroenterology/Urology	Gastroenterology/Urology	Yes
Indications for use	The DEFENDO™ Y-Opsy Irrigator is intended to enable simultaneous irrigation and instrumentation in the endoscope's biopsy channel.	The EndoGator System® (tubing and accessories to accommodate various endoscopes and irrigation pumps) is intended to provide irrigation via sterile water supply during GI endoscopic procedures when used in conjunction with an irrigation pump (or cautery unit).	The DEFENDO™ Biopsy Valve is indicated for covering the endoscope biopsy port during an endoscopy procedure. In addition, the valve provides access for endoscopic device passage and exchange, helps maintain sufflation and minimizes leakage of biomaterial from the biopsy port throughout the endoscopic procedure.	Yes
Compatible Endoscope(s)	Olympus & Fujinon endoscopes	Olympus & Fujinon endoscopes	Olympus & Fujinon endoscopes	Yes
Patient Population	Patients who are undergoing an endoscopy	Patients who are undergoing an endoscopy	Patients who are undergoing an endoscopy	Yes
Environment of Use	Hospital and/or Clinic	Hospital and/or Clinic	Hospital and/or Clinic	Yes
Manufacturing method	Injection molded	Injection molded	Injection molded	Yes
Opening for Instruments	Slit in diaphragm	Y-Connector	Slit in diaphragm	No
Reusable or disposable	Disposable	Disposable	Disposable	Yes
Sterile	Yes	Yes	Yes	Yes

Similarities and Differences:

Similarities: Indications for Use

All three products cover a biopsy port, provide access for endoscopic device passage and exchange, and help maintain sufflation, minimize leakage of biomaterial from the biopsy port throughout the endoscopic procedure and provide access for irrigation.

All three devices are suitable for use with both the Olympus and Fujinon endoscopes.

All three devices have the same Regulation number (876.1500) and all are Class II medical devices. All three are intended for the same patient population and environment of use.

Differences:

The Endogator® System is comprised of a peristaltic pump, tubing, and accessories, one of which is a Y-Connector. All these components are connected to the endoscope and work in unison, to provide for irrigation and allow for instrument passage into the colon. The DEFENDO™ Y-Opsy and DEFENDO™ Biopsy Valve are more of a "stand alone" product. The DEFENDO™ Y-Opsy connects directly to the biopsy port of the endoscope and allows for the passage of instrumentation such as biopsy forceps through the slit in the valve while also allowing for irrigation through a separate channel.

The DEFENDO™ Biopsy Valve also connects directly on to the endoscope biopsy port and only allows for passage of instrumentation such as Biopsy forceps through the slit in the valve.

Comparative Studies: Bench Testing

In a comparison of flow rates between the DEFENDO™ Y-Opsy Irrigator and the predicate, Endogator System Y-Connector utilizing two separate manufacturers' endoscopes, the DEFENDO™ Y-Opsy demonstrated equivalent or greater flow rate than that of the predicate.

In a comparison study between the DEFENDO™ Y-Opsy Irrigator and the predicate, the DEFENDO™ Biopsy Valve utilizing five functional criteria, the DEFENDO™ Y-Opsy Irrigator demonstrated equivalent performance to the DEFENDO™ Biopsy Valve.

Leak Testing:

Leak testing was performed with the DEFENDO™ Y-Opsy Irrigator to simulate the withdrawal of biopsy samples, bowel irrigation and bowel insufflations. 100% of the DEFENDO™ Y-Opsy Irrigators tested showed no evidence of fluid leakage during sample biopsy or bowel irrigation.

Additionally, tests were performed simulating bowel insufflations, 100% of the DEFENDO™ Y-Opsy Irrigators tested maintained a pressure of at least 10 psi with no leakage.

Based on the above findings we have determined that the DEFENDO™ Y-Opsy Irrigator is substantially equivalent to its predicates, the Endogator® System Y-Connector (K092429) and the DEFENDO™ Biopsy Valve (K090851).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G609
Silver Spring, MD 20993-0002

JUN 10 2011

Mr. John Willis
Director of Regulatory Affairs
Byrne Medical, Inc.
3150 Pollok Drive
CONROE TX 77303

Re: K110088
Trade/Device Name: DEFENDO™ Y-Opsy Irrigator
Regulation Number: 21 CFR §876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: ODC
Dated: May 4, 2011
Received: May 5, 2011

Dear Mr. Willis:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related

adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Herbert P. Lerner, M.D., Director (Acting)
Division of Reproductive, Gastro-Renal
and Urological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known) K110088

Device Name: DEFENDO™ Y-Opsy Irrigator.

Indications for Use:

The DEFENDO™ Y-Opsy Irrigator is intended to enable simultaneous irrigation and instrumentation in the endoscope's biopsy channel.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Gastro-Renal, and Urological Devices
510(k) Number K110088